VZCZCXRO3373
PP RUEHAG RUEHAST RUEHDA RUEHDBU RUEHDF RUEHFL RUEHIK RUEHKW RUEHLA
RUEHLN RUEHLZ RUEHROV RUEHSR RUEHVK RUEHYG
DE RUEHLJ #0103/01 0521346
ZNR UUUUU ZZH
P 211346Z FEB 07
FM AMEMBASSY LJUBLJANA
TO RUEHC/SECSTATE WASHDC PRIORITY 5566
INFO RUEHZL/EUROPEAN POLITICAL COLLECTIVE
RUCPDOC/DEPT OF COMMERCE WASHDC

UNCLAS SECTION 01 OF 03 LJUBLJANA 000103

SIPDIS

SENSITIVE
SIPDIS

DEPT FOR EUR/NCE (SSADLE), EB/TPP/IPE (JBOGER)
STATE PLEASE PASS TO USTR LERRION

E.O. 12958: N/A
TAGS: ECON ETRD KIPR SI
SUBJECT: SLOVENIA: 2007 SPECIAL 301 REVIEW - RECOMMENDATION AGAINST INCLUSION ON WATCHLIST

REF: STATE 07944

¶1. (SBU) SUMMARY: As of 2006, Slovenian legislation on intellectual property rights is fully aligned with EU legislation, TRIPS and ratified international treaties, and in practice, U.S. pharmaceutical companies have access to the Slovene market. Recent efforts by the Government of Slovenia (GOS) to balance the health-care budget have posed some problems for "innovative" drug producers. But it appears that the long-term impact of the legislation will be to expand the availability of drugs, including innovative drugs, to the Slovene public. Post is encouraged by the Ministry of Health's (MOH) recent incorporation of PhRMA and Post's pricing concerns in a recent regulation. Post believes GOS cooperation will continue to increase, and that Slovenia does not warrant inclusion on the Special 301 Watch List. END SUMMARY.

¶2. (U) INTELLECTUAL PROPERTY: Slovenia has in place necessary legal protections for intellectual property rights and provides adequate protection according to TRIPS standards. Slovenian legislation provides for different legal measures within the framework of civil, criminal and administrative law, which may be used by holders of intellectual property rights to defend their interests. The Industrial Property Act(IPA), the Act on Litigation Procedure (ALP) and the Act on Enforcement of Judgments in Civil Matters and Insurance (AEJCMI) are generally used in civil litigation and for cases involving infringement of industrial property rights. In 2007 SIPO revamped its website so that both domestic and foreign parties can access the most current information regarding intellectual property issues.

¶3. (U) COURT PROCEDURES: PhRMA's continued complaint about slow court procedures in Slovenia is well-founded but does not reflect the progress that Slovenia has made in the past few years. In December 2005, the Ministry Of Justice (MOJ) announced the Lukenda Project, a plan to eliminate judicial backlog by 2010. The plan called for the hiring of 500 auxiliary court staff, upgrading courtroom technology and streamlining small claims cases. Results of the Lukenda project have been encouraging -- increased numbers of cases have been resolved, average time of proceedings has already been reduced significantly, and all small claims cases filed before December 2005 have been adjudicated. Over the next five years, the program will cut the average processing time of a case from 18 months to 6 months. Additionally, a number of alternative dispute resolution mechanisms have been introduced in order to alleviate pressure on the court system. The Slovenian Intellectual Property Office (SIPO) acknowledges deficiencies in Slovenia's legal system, but denies that current legislation favors domestic

(pharmaceutical or other) industry.

¶4. (U) To support the efforts of the GOS, Post has funded and coordinated several training programs for Slovene judges, prosecutors, and police, with several more to take place in ¶2007. Post believes that providing US expertise is helping to create a more efficient judicial system, which could help improve the speed of case adjudication in the courts.

¶5. (U) FREE CHOICE OF EXPERTS: If expert testimony is deemed necessary, the court may designate one or more experts, generally after consultation with both parties. The court generally designates a "court expert" - someone already deemed by the court to have qualifications necessary to comment authoritatively on the subject of the case - and will pay the expenses of this expert. It is also possible for the court to designate a person or institution which is not considered a "court expert," but an expert in the subject nonetheless, including a foreign person or institution. Additionally, experts may be proposed by the parties, but the costs associated with the proposed expert must be covered by the proposing party.

¶6. (U) PIPELINE PROTECTION: Pipeline protection is not a TRIPS obligation. Slovenia introduced patent protection on January 1, 1993. Prior to this, there was no protection either in Slovenia or the former Socialist Republic of Yugoslavia of which Slovenia was a part until June 25, 1991. At the other end of the spectrum, Slovenia introduced the possibility of supplementary protection certificates in 1993. Since May 1, 2004, when Slovenia joined the EU, supplementary protection certificates have been granted in accordance with European regulations. Patent holders have the possibility to claim prolonged protection for a product after the expiration of patent protection.

¶7. (U) MARKET ACCESS BARRIERS: The GOS has been focused on controlling government spending in preparation for joining the euro zone (which it accomplished in January 2007). The Ministry of Health's (MOH) goal, as part of health-care reforms, was to control healthcare costs. In January 2007, the MOH adopted some changes to drug reimbursement procedures. Slovenia now employs a pricing and reimbursement system based on manufacturer prices for drugs in Germany, France, and Austria (previously it used Germany, France and Italy as its reference points), taking into account Slovenia's lower GDP. While PhRMA acknowledges that regulating pricing at the manufacturer level increases transparency, it is still dissatisfied with the reimbursement procedure. Slovenian officials question PhRMA's claim that the reimbursement procedures followed in Slovenia fall under the guidelines of the EU directives on transparency. Post understands that Slovenia's program, while perhaps not ideal, is a legitimate formula not unlike those used in other EU member states.

¶8. (U) Slovenia's approach on drug pricing has been an effort to find a balance between the use of innovative and generic drugs. Contacts at the MOH have told Post that PhRMA's complaint on favoring domestic producers over foreign was not justified and that the pricing measures were not specifically aimed at foreign producers. Post understands that domestic Slovene generic producers also are experiencing increased competition with the introduction of lower priced generic drugs from India.

¶9. (U) PRICING: PhRMA complains that Slovenia is inconsistently and non-transparently applying the Anatomical Therapeutic Chemical (ATC) and Defined Daily Dose (DDD) systems. Post understands that the MOH uses the ATC/DDD as indicators, not exclusive determinants, of price. Contacts at the Ministry tell Post that there is no law or legal procedure prohibiting physicians from prescribing any drug approved for use in Slovenia. However, the system will only

reimburse up to the value of the lowest-priced drug on the Interchangeable Drug List (IDL). This system would not affect any new, innovative drugs brought to market before the patent protection period ran out and generics became competitive.

¶10. (U) The MOH has told Post in the past that the changes in regulations have all been adopted in order to control healthcare costs and make decision-making more transparent. These decisions have significantly decreased the annual percentage rise in the Government's expenditures on healthcare. Post understands that the Ministry sees this current period as one of adjustment. Health Minister Andrej Brucan, as he unveiled the new pricing regulations on January 23, stated that his goal is to use the increased savings to improve health services and to spend more on innovative drugs.

¶11. (SBU) COMMENT: In general, it appears that the GOS is meeting its obligations under TRIPS and the 24 other treaties on intellectual property and patents to which it is party. With membership in the EU, there is added pressure to conform to European norms, and it is Post's opinion that Slovenia is making progress and will continue to do so in good faith, even if in some areas it has yet to achieve this goal. The most significant problem, by far, is an overburdened court system, which is also the target of many calls for reform from all sectors of society. COM continues to make judicial reform a theme in his discussions with senior government officials and representatives of the judicial system. Post's success in facilitating judicial training should also help Slovenia in its efforts to improve the efficiency of its courts. In addition to the IPR complaints, PhRMA has pointed to the problem of market access and drug cost reimbursement policies in the Slovene health system. There is agreement on all sides that the reimbursement mechanism employed by the Slovene health system has disadvantaged some innovative drug producers in some categories in the short run. This development, however, should be viewed in the context of the overall need for the GOS to balance its budget, bring down inflation, and root itself in the euro zone, which it joined in January 2007. The measures were not undertaken with a goal of favoring domestic producers of generic drugs, and according to the GOS, Slovenia's system is similar to the majority of EU members' systems.

¶12. (SBU) Post hopes this information will be helpful in stimulating a well-informed discussion of PhRMA's claims. Post is committed to promoting a fair, open and transparent market for U.S. pharmaceuticals. We are in regular contact

with the local PhRMA and are prepared to engage further with the GOS on all of the issues raised by PhRMA. For 2007, utilizing lessons learned when PhRMA and Post successfully engaged the GOS to ensure a fairer pricing plan, PhRMA and Post are working together to proactively promote fair market access and find the most effective ways in which PhRMA and Post can lobby the GOS. We look forward to engaging in further dialogue on this issue, and, as always, we welcome guidance from both USTR and the Department. END COMMENT.

ROBERTSON